

INTRAURETHRAL MAGNETIC VALVE AND METHOD AND TOOL  
FOR IMPLANTING, EXTRACTING, AND MANIPULATING SAID VALVE  
IN THE URETHRA

This application claims priority to U.S. Provisional Application No. 60/543,188, filed February 10, 2004, and is herein incorporated by reference.

Field of the Invention

The present invention relates to an intraurethral magnetic valve, and particularly to an intraurethral magnetic valve for insertion into the urethra of a person's body to selectively provide fluid discharge therefrom and to spontaneously provide high-pressure relief. The invention further relates to a method and tool for implanting, extracting, manipulating and irrigating the intraurethral magnetic valve within the urethra of a person's body. Such tool may be used with other valves or devices adapted for engaging the tool.

Background of the Invention

Devices for implanting and removing intraurethral sphincter prostheses for treatment of urinary retention have been developed using devices for detecting, gripping and positioning valves and stents within the urethra, as described in U.S. Patent Nos. 3,642,004, 5,041,092 and 5,112,306, or use multilumen devices for inflating and deflating stent fixating balloons, as described in U.S. Patent No. 5,964,732. Also developed have been separate tools for insertion and extraction, and tethers for retrieval of valves and stents, as described, for example, in U.S. Patent No. 6,551,304. These devices for implanting and removal of intraurethral devices are complex and do not provide immediate confirmation of proper placement in the urethra. Such immediate confirmation is desirable to avoid possible patient complications due to misplacement, or additional procedures to replace the prosthesis. Further, often these devices lack means to irrigate and cleanse intraurethral valves and stents, which can become fouled with renal calculus and tissue debris, and also do not provide needed accommodation for gross misalignment caused by bends and anatomical structures within the urethra to assure trauma free engagement with stent or valve during extraction.

Conventional intraurethral sphincter prostheses for treatment of urinary retention have used the interaction of internal and external magnets to open and close valves variously fixed within the urethra either surgically or within stents, catheters or urethral plugs. These magnetic interactions have generally displaced a valve check along a straight two dimensional path to permit fluid flow, see for example, U.S. Patent Nos. 3,642,004, 3,812,841, 5,030,199, and 6,632,421. Additionally U.S. Patent No. 6,527,702 shows the use of the magnetic interaction

indirectly by inflating or deflating a closure mechanism or to rotate threaded valve stems or keyed journals, see also U.S. Patent Nos. 6,221,060 and 6,417,750.

U.S. Patent Nos. 5,366,506 and 6,066,088 issued to the present inventor, permit the valve check to move in an arbitrary, three-dimensional path. This free movement reduces friction effects and permits construction with few parts and simple geometric shapes. It also permits great flexibility and inaccuracy in the positioning of external actuating magnets and long working distances for those actuators. This flexibility enables an implant recipient having limited manual dexterity due to spinal cord injury or other neurological impairment to successfully operate the valve with a hand held switching magnet. In U.S. Patent No. 5,366,506 however, this freedom of check movement may restrict valve aperture diameter and thus can limit flow rates. Additionally, the freedom of movement prevents inclusion of a high-pressure relief mechanism.

#### Summary of the Invention

One feature of the present invention is to provide an improved intraurethral valve housing and insertion/extraction tool which, when combined, provide simple placement and manipulation of valves, stents and valved stents in the human urethra, and which are highly tolerant of misalignment of valve and insertion/extraction tool, and provide for irrigating and cleansing intraurethral valves, stents and valved stents.

Another feature of the present invention is to provide an improved intraurethral valve having increased flow rate of the valve by reducing drag at its inlet aperture and valve seat.

It is a further feature of the present invention to improve the intraurethral valve of U.S. Patent No. 5,366,506 by providing for high-pressure relief in the event of medically dangerous intravesical pressures.

Briefly described, the intraurethral magnetic valve embodying the present invention includes a nonferromagnetic cylindrical housing having inlet and outlet ends, a nonferromagnetic valve seat sealingly attached to the inner wall of the housing between the inlet and outlet ends, a cylindrical valve element disposed for universal movement within the housing between the nonferromagnetic valve seat and the inlet end of the housing containing a high coercivity permanent magnet, a ferromagnetic valve seat disposed for axial movement within the housing between the nonferromagnetic valve seat and the outlet end of the housing, a compression spring disposed to maintain the ferromagnetic seat in contact with the nonferromagnetic seat, a retaining ring at the inlet end of the housing for maintaining the valve element within the housing, and a pair of flanges at the outlet end of the housing for maintaining compression on the spring. The flanges at the outlet end of the housing may be

used for engaging an insertion/extraction tool to implant and remove the valve from the urethra.

The ferromagnetic valve seat is free to move axially away from contact with the nonferromagnetic seat by additional compression of the spring in response to high fluid pressure. This movement breaks the fluid seal between ferromagnetic and nonferromagnetic seats and permits fluid to escape through gaps between the ferromagnetic seat and housing, relieving medically dangerous excess intravesical pressure without intervention by an operator.

The nonferromagnetic valve seat has a sloping inner wall with a plurality of flanges, which guide the freely moving valve check to concentric alignment with the ferromagnetic seat when in the normally closed position. By returning the check to this central position when closed, it is possible to maximize seat aperture diameter and thus maximize flow rate when open. In contrast, U.S. Patent No. 5,366,506 allows an arbitrary alignment of the valve check when closed, requiring a reduction in aperture diameter to accommodate all possible closure positions and further prohibiting inclusion of a high-pressure relief mechanism. The present invention provides omnidirectionality of valve opening in response to an external hand held magnet, while maximizing aperture diameter and providing high-pressure relief. U.S. Patent No. 6,066,088, describes a spherical valve check and concave valve seat which are by nature self centering.

In response to a hand held or other external switching magnet, the cylindrical valve element moves arbitrarily within the confines of the housing, inlet end retaining ring, and combined ferromagnetic and nonferromagnetic seats, opening the valve to fluid flow. The gross dimensions of this confining space are selected so that at all possible open positions the sum of friction forces at the contact points of valve element and both ferromagnetic and nonferromagnetic seats is not sufficient to hold the valve open on removal of the switch magnet.

The insertion/extraction tool of the present invention has a tip with a frustoconical point along which extend flanges to enable insertion of the tip into an outlet aperture of the valve, such outlet aperture has flanges providing a keyed opening alignable with the flanges of the tip, in which rotation of the tip in a first rotational direction locks the tip onto the device and in the opposite rotational direction unlocks the tip from the device. A cylindrical segment extends from the tip and is attachable to a length of tubing. The tubing when attached to the cylindrical segment provides a conduit for bi-directional fluid flow through a lumen, which extends through the tip and the cylindrical segment into such tubing. The tubing further provides means for extracorporeal manipulation of the device when locked to the tool.

A method for manipulating devices, such as valves and other apparatus, with the

insertion/extraction tool in the urethra of a patient is also provided. This method has the steps of: providing a tool having a tip with flanges insertable into an aperture of a device and tubing extending from the tip; inserting the tip and tubing into the aperture in which the aperture has flanges providing a keyed opening alignable with the flanges of the tip; rotating the tubing in a first rotational direction to lock the tip onto the device; inserting and positioning the device locked to the tool in the urethra of a patient by manipulating the tubing; rotating the tubing in the opposite rotational direction to unlock the tip from the device; and removing the tubing and tip from the urethra of the patient leaving the device within the urethra. Irrigation and back flushing can take place via the tubing with the aid of a lumen extending through the tip. To extract the device from the urethra, the method further has the steps of: inserting the tip and tubing in the urethra of the patient; locating the tip in the aperture of the device; rotating the tubing in a first rotational direction to lock the tip onto the device; and removing the device locked to the tool from the urethra of the patient.

The present invention is further directed to improvements in U.S. Patent Nos. 5,366,506 and 6,066,088 to provide improved manipulating means and to simplify stent design. U.S. Patent No. 5,366,506 provides a single chamber within the housing to hold the valve element and to receive an insertion/extraction tool. As the valve element travel is limited to a few tenths of millimeters, which space is shared with the insertion/extraction tool, that tool is required to have a thin planar face. A planar tip can only enter and engage the flanged housing if perfectly aligned with that housing. The nonferromagnetic frustoconical, flanged tip of the tool described herein can locate and guide itself into the housing despite gross misalignment. The housing of the present invention has an additional chamber space within the valve providing room for the frustoconical tip independent of the valve element travel-limiting chamber of U.S. Patent No. 5,366,506. Other valves may be placed in the housing of the present invention leaving a similar additional chamber for the frustoconical tip of the tool. U.S. Patent No. 6,066,088 provides for the use of an insertion/extraction tool that engages soft, elastomeric material of stent end flanges rather than valve end flanges. The present invention improves U.S. Patent No. 6,066,088 by permitting the insertion/extraction tool to engage the valve housing enabling higher force levels needed for difficult intraurethral manipulations and eliminating the stent end flanges.

As an alternative embodiment, separate insertion and extraction tools may be provided having nonferromagnetic and ferromagnetic frustoconical tips, respectively. During extraction, the ferromagnetically tipped extraction tool is used to draw to centered alignment with the valve housing by attraction to the magnetic valve element. The insertion tool has a nonferromagnetic tip to assure free disengagement from the valve during implantation. Or, a

single insertion/extraction tool may be used with two replaceable tips, one ferromagnetic for extraction, and the other nonferromagnetic for implantation.

The housing of the present invention includes a nonferromagnetic biocompatible cylindrical tube of sufficient diameter to contain valve elements within and of sufficient strength and rigidity to hold those elements in fixed relationship to each other. Integral to the housing is a pair of flanges at the outlet end shaped to make loose fitting engagement with an insertion/extraction tool used to implant and remove devices from the urethra. The flanges are further shaped to mate with the above mentioned insertion/extraction tool despite gross misalignment and to engage with the tool after minimal tool rotation. The housing flanges and the engagement flanges of the insertion/extraction tool interfere with each other, and do not provide friction fit, threaded fit, or fluid seal. As such, they cannot jam or lock together making it impossible to separate the tool and valve within the urethra. Also, because they do not provide fluid seal, they can be used with any valve or stent to test urine flow during placement and manipulation. An optional elastomeric washer may be provided for the tool which provides an intentionally imperfect sealing member. Imperfect sealing permits valve irrigation at elevated pressure without risk of jamming tool and housing together.

#### Brief Description Of The Drawings

The foregoing features and advantages of the invention will become more apparent from a reading of the following description in connection with the accompanying drawings in which:

Fig. 1 is a sectional view taken through the normally closed intraurethral magnetic valve in accordance with the present invention;

Fig. 2 is a sectional view through the valve of Fig. 1 showing the path of fluid flow when open with an example of an arbitrary open position of the valve element assembly by its attraction to an external magnet;

Fig. 3 is a sectional view through the valve of Fig. 1 showing the path of fluid flow during high-pressure relief by movement of the ferromagnetic valve seat;

Figs. 4A and 4B are an inlet end view and sectional view, respectively, of the housing of the valve of Fig. 1 without internal components and retaining ring;

Figs. 5A and 5B are end and sectional views, respectively, of the nonferromagnetic valve seat of the valve of Fig. 1;

Figs. 5C and 5D are end and sectional views, respectively, similar to Figs. 5A and 5B of an alternate embodiment of the nonferromagnetic valve seat;

Figs. 6A and 6B are end and sectional views, respectively, of the ferromagnetic valve

seat of the valve of Fig. 1;

Fig. 7 is a sectional view of the valve element assembly of the valve of Fig. 1;

Fig. 8 is a sectional view of the inlet retaining ring of the valve of Fig. 1;

Figs. 9A and 9B are end and side views, respectively, of the tip of an insertion/extraction tool which may be used to engage the outlet end flanges of the valve of Fig. 1, and housing of Figs. 4A and 4B;

Figs. 9C is a schematic side view of the insertion/extraction tool having the tip of Figs. 9A and 9B coupled to a length of catheter tubing;

Fig. 10A is an alternative embodiment of the tip in Figs. 9A-9C;

Figs. 10B and 10C are side views of the insertion/extraction tool tip of Figs. 9A-9C rotated 10 degrees and 90 degrees, respectively;

Fig. 11A is a sectional view of the tip of Fig. 10B;

Fig. 11B shows the tip of Fig. 11A engaged in the housing of Fig. 4A;

Fig. 11C is a partial view of the insertion/extraction tool tip of Figs. 9A-9C entering the distal end of valve housing of Fig. 1, shown also in partial view, while grossly misaligned with the housing;

Fig. 12A is a schematic view of the valve of the Fig. 1 secured in the distal end of an intraurethral stent and fully engaged with the insertion/extraction tool of Figs. 9A-9C;

Fig. 12B is a schematic view of insertion/extraction tool of Figs. 9A-9C in the stent and valve of U.S. Patent No. 6,066,088, said valve being adapted to receive and engage such tool;

Fig. 12C is a schematic view of the housing of Fig. 1 secured in the distal end of an intraurethral stent in which no valve components of Fig. 1 are provided therein;

Figs. 13A and 13B are end and sectional views respectively of an optional washer which may be used on the insertion/extraction tool of Figs. 9A-9C for increasing irrigation pressure of fluid delivered through the tool; and

Fig. 13C is a side view of the irrigation washer of Figs. 13A and 13B affixed to the tool tip of Figs. 9A-9C.

### Detailed Description of the Invention

Referring to Fig. 1, a valve assembly 1 shown in its normally closed position having a cylindrical nonferromagnetic housing 2 having a continuous sidewall 3. A ferromagnetic valve seat 4 of high magnetic permeability is sealingly held against a nonferromagnetic valve element guide (or seat) 5 by compression spring 6. Valve element guide 5 is sealingly and fixedly held against housing sidewall 3. The valve element guide 5 is described in more detail later in connection with Figs. 5A-5D. A valve element assembly 7 is sealingly held against

valve seat 4 by magnetic attraction of magnet 8 to ferromagnetic seat 4. Valve element assembly 7 is described in more detail later in connection with Figs. 7 and 8. A nonferromagnetic retaining ring 9 limits movement of valve element assembly 7 when under the attraction of an external hand held magnet 50 (Fig. 2). Retaining ring 9 is fixed to the inlet end of housing 2 and has an inlet aperture 10 for urine. Housing 2 has flanges 11 which maintain compression of spring 6, and can engage an insertion/extraction tool 12 shown later in Figs. 9, 10, and 11. Housing distal end 2a has an outlet aperture 13 defined by flanges 11 and sidewall 3 to permit urine to flow out of the valve and permit the insertion/extraction tool 12 to enter the valve. Spring 6 is made of, or plated with, biocompatible material and is positively compressed to provide sufficient bias force to resist displacement of seat 4 under the influence of normal and safe intravesical pressures at inlet aperture 10 when valve assembly 1 is installed in the urethra of a human patient.

Referring to Fig. 2, the valve assembly 1 is shown with valve element assembly 7 (also known as a valve check) in an example of an arbitrary open position when under magnetic torque or attraction force induced by external hand held magnet 50 (shown not to scale). The internal magnet 8 is normally attracted to ferromagnetic seat 4 causing the valve element assembly 7 to cover and occlude seat aperture 32. The external magnet 50 induces torque and attraction on the magnet 8 causing the valve element assembly 7 to tip away from seat 4 breaking the fluid seal between the valve element assembly 7 and the valve seat 4. For example, an arrow 100 from inlet aperture 10 to outlet aperture 13 via aperture 32 indicates urine flow path. To prevent jamming in an open position, the gross dimensions of valve element assembly 7 are chosen so that in all possible open positions a maximum of three contact points with other valve assembly elements are possible. These contacts may be: a rounded edge 17 of valve element 7 touching both valve seat 4 and guide 5 while a square edge 18 touches sidewall 3; or square edge 18 touching retainer 9 and sidewall 3 while rounded edge 17 contacts sloping wall 19 of guide 5. In the general open position, there are only two contact points which are subsets of the above three point combinations. In all possible open positions the valve element assembly and seat contact angles are limited so that the sum of friction forces on edge 17 tending to hold the valve open is less than the magnetic forces tending to spontaneously close the valve by occluding aperture 32 on withdrawal of the hand held switch magnet 50.

Referring to Fig. 3, valve assembly 1 is shown in the pressure relief position. Urine hydrostatic pressure at inlet 10 in excess of medically safe intravesical pressures overcomes spring 6 bias compression and displaces seat 4 from sealing engagement with the sealing face 14 of guide 5. Valve element assembly 7 displaces with seat 4. Urine then flows through the

gaps 15 between guide 5 and valve element assembly 7 and through gaps 16 between seat 4 and housing sidewall 3. Gaps 16 are shown in greater detail in Fig. 6A. For example, an arrow 101 from inlet aperture 10 to outlet aperture 13 via gaps 15 and 16 indicates urine flow path. Displacement of seat 4 and gaps 15 and 16 are shown exaggerated in Fig. 3 for purposes of illustration. Flow rate is low due to the narrow gaps, but sufficient to relieve bladder pressure.

Referring to Figs. 4A and 4B, two flanges 11 form crescents on the distal outlet end of housing 2. Generally circular arches 22 provide passageway for the generally conical tip of insertion/extraction tool 12 shown in detail in Figs. 9A-9C. Flat surfaces 23 act as rotational stops and engagements areas for tool 12 of Figs. 9A-9C. Groove 24 passing twice through housing sidewall 3 is optional and is merely a manufacturing convenience. Housing 2 is made of nonferromagnetic, biocompatible material.

Referring to Figs. 5A and 5B, guide 5 is shown with an opening 5a and a plurality of sloping tabs 25. Three or more tabs 25 are preferred. Their sloped surfaces 19 can contact valve element assembly 7 rounded edge 17 of Figs. 1 and 7 and guide that assembly to roughly concentric alignment with valve seat 4 of Fig. 1. By returning the valve element assembly to a central (or approximately central) position when closed, the valve seat aperture 32 can be maximized resulting in maximized fluid flow rate. Guide 5 may represent a ring cut down in areas 26 interleaved with tabs 25 to provide extra clearance for fluid flow around valve element assembly 7, further reducing drag and increasing flow rate. Surfaces 27 of interleaved areas 26 are relieved below surfaces 19 sufficiently to prevent contact of valve element assembly 7 with edges 28 which would prevent spontaneous valve closure. Surface 14 of guide 5 is sufficiently flat and smooth to form a noncompliant fluid seal with surface 21 of valve seat 4 at hydrostatic pressures normally found in the human bladder and under the bias contact force provided by spring 6 of Fig. 1. A compliant seal is an optional alternative embodiment. The outer surface of guide 5 has a diameter that frictionally engages the interior of wall 3 of housing 2. Guide 5 is made of nonferromagnetic, biocompatible material. However, other material less preferably may be used for housing 2 and guide 5 which may have low magnetic permeability.

Referring to Figs. 5C and 5D, an alternative embodiment of the guide 5 is shown lacking cut down areas 26 of Figs. 5A and 5B. This provides a guide 5 with an annular sloped interior surface about opening 5a of reducing diameter in the distal direction. This may result in simplicity of manufacture, but at a slight reduction in flow rate.

Referring to Figs. 6A and 6B, the valve seat 4 of Fig. 1 is shown. The seat 4 is made of ferromagnetic material having high magnetic permeability and is made of, or plated with,

biocompatible material. Surface 21 is sufficiently flat and smooth to form noncompliant fluid seals with valve element assembly 7 and surface 14 of guide 5 of Fig. 1 at hydrostatic pressures normally found in the human bladder and under the bias contact force provided by spring 6 and magnetic attractive force provided by the valve element assembly. Compliant seals are optional alternative embodiment. Shoulders 29 fit loosely within housing sidewall 3 permitting axial movement of seat 4 away from guide 5, breaking the seal between surfaces 21 and 14 and thus providing pressure relief as described earlier. Three shoulders 29 are shown radially spaced along the outside cylindrical surface of seat 4. Fluid flow is through narrow reliefs (or recesses) between shoulders 29, such reliefs provide gaps 16 described earlier. Depression 30 fixes compression spring 6 in concentric alignment with seat 4 as shown in Fig. 1. Bevel 31 on distal side of seat 4 reduces fluid drag through aperture 32.

Referring to Fig. 7, the valve element assembly 7 is shown in sectional view. Can 33 is generally cylindrical and made of nonferromagnetic, biocompatible material. Can 33 may represent a container with an open end through which a cylindrical permanent magnet 8 is received. The dimensions of the magnet 8 may be such that it fills or substantially fills the entire can but for a cap 36 received in the open end of can 33. The cap may be held by adhesive, friction, or both in the can 33. Surface 20 is sufficiently flat and smooth to form a noncompliant fluid seal with valve seat 4 of Fig. 1 at hydrostatic pressures normally found in the human bladder and under the contact force provided by attraction of magnet 8 to valve seat 4. Web (or wall) 35 thickness is carefully controlled to limit this attractive force. Cylindrical permanent magnet 8 is axially polarized with arbitrary polarity. Can 33 has an edge 17 slightly rounded to prevent entanglement with scratches or machining imperfections in seat 4 and guide 5 and to assure consistent friction forces between the can 33 and those elements. Cap 36 may be of nonferromagnetic, biocompatible material and prevents contact of urine with magnet 8. As an alternative embodiment, cap 36 and can 33 may be eliminated and the magnet 8 coated with biocompatible material sized to the dimension of can 33.

Referring to Fig. 8, the retaining ring 9 of Fig. 1 is shown in sectional view through its centerline with valve element assembly 7 shown in a typical open position. The ring is made of nonferromagnetic, biocompatible material. In this figure, inlet aperture 10 (FIG. 1) is represented by central aperture 38. The central aperture 38 diameter is limited so that at all possible open positions, edge 18 of valve element assembly 7, cannot fall within aperture 38, but must instead contact the ring on surface 39. Inlet side of aperture 38 has bevel 40 to reduce fluid drag.

Referring to Figs. 9A, 9B and 9C, the insertion/extraction tool 12 is shown. The tool 12 has at one end a tip 12a which is received into a catheter tubing 51. The tip 12a is made of

nonferromagnetic biocompatible material. However, other biocompatible material may be less preferably used which have some ferromagnetic properties. For purposes of illustration, most rounding and filleting necessitated by machining practices or to prevent laceration of the urethra have been omitted from these figures. In practice, all corners and edges are preferably broken and smoothed. Tip 12a has a frustoconical point 40 and a lumen or opening 41, which extends from the frustoconical point 40 through the tip 12a and into tubing 51, to provide a path for urine flow through the entire length of the tip and a path for upstream irrigation if needed. Two flanges 42 emerge from a cylindrical segment 43 of tip 12a terminating at their intersections with conical tip surface 44. Flanges 42 engage flanges 11 of housing 2 (Fig. 1), and are used to pull on the valve assembly when extracting it from or positioning it in the urethra. Stop flanges 45 limit rotation of the tip 12a within housing 2 by interference with flanges 11 and transmit torque to rotate housing and stent 60 (see Fig. 12A and 12C, or Fig. 12B with respect to rotation of housing 109) within the urethra. Maximum tip rotation within housing 2 is less than 45 degrees. Shoulder 46 limits penetration of the tip into housing 2 and is used to push the valve into the urethra during implantation and positioning. The tip 12a has a cylindrical segment 47 which fits securely (by frictional engagement) in catheter tubing 51 shown sectioned and truncated in Fig. 9C which extends outside the body and is used to manipulate tip and engaged valve and may be used to irrigate the valve. Lumen 41 extends through the tip 12a and its cylindrical segment 47 as shown by dashed lines in Fig. 9B. Shoulder 46 is annularly disposed around cylindrical segment 43 between cylindrical segment 47 and flanges 42 and 45. Catheter tubing 51 may be of rubber, plastic, or other biocompatible material which can pass torque from one end of the tubing to the tip 12a at the other end of the tubing.

As an alternative embodiment, when tool 12 is used as an extraction tool, the tip 12a may be made of ferromagnetic material so that it is drawn to and aligned with the valve housing by magnetic attraction to the valve element. Two separate tools may be provided, a first tool with a ferromagnetic tip for extraction of the valve, and the second with a nonferromagnetic tip for implantation of the valve. Or, a single tool may be provided with replaceable ferromagnetic and nonferromagnetic tips 12a, which releasably engage (such as by friction) in the end of tubing 51, or these tips have detents or tabs along the outside of segment 47 which lock or latch into openings in tubing 51 when each tip is inserted in the tubing.

Referring to Fig. 10A, cylindrical segment 47 of the tip shown in Fig. 9B may, as an alternative embodiment, be barbed with a plurality of barbs 48, as shown to provide secure fixation within catheter tubing 51.

Referring to Figs. 10B and 10C, the tip 12a of Fig. 9B is shown rotated 10 degrees and

90 degrees, respectively, to better show flanges 42 and 45. When the tool tip 12a is engaged with a valve housing, as shown in Fig. 11B, flanges 42 may be used to pull on the valve housing 2 by contact against flanges 11. Similarly, when engaged, tip rotation within the housing is limited and torque transmitted to the housing by contact of surfaces 59 (Fig. 10B) of stop flanges 45 (Fig. 4A) against surfaces 23 of flanges 11, providing means to rotate housing 2 and stent 60 (Figs. 12A or 12C), in which housing 2 (or housing 109 of Fig. 12B) is located within the urethra. In this manner, tip 12a provides a key which may be inserted through keyed opening 13 and rotated in a first direction to lock tool 12 to housing 2 and facilitate placement by a physician or other trained person in the urethra of a patient, in which when the housing 2 is properly positioned in the urethra, reverse rotation in the opposite direction unlocks the tool 12 which then can be removed through opening 13 and exit the urethra.

Referring now to Fig. 11A, for purposes of illustration a sectional axial view of tip 12a of Fig. 10B is shown. Further referring to Fig. 11B, the tip 12a of Fig. 11A is shown in bold line fully engaged with housing 2 flanges 11. In this position it can be used to push, pull and counterclockwise rotate the valve.

Referring to Fig. 11C, the Fig. 10B profile view of the tip 12a is shown entering outlet aperture 13 (FIG. 4) of housing 2, while grossly misaligned with housing 2. Tip conical surface 44 and housing aperture arches 22 (Fig. 11B) enable tip 12a to locate and enter housing 2 despite severe misalignment. When used as an extraction tool within the urethra, tip 12a must accommodate misalignment due to urethral bends and anatomical structures in order to locate and enter housing 2. When used as an insertion tool, this misalignment capability permits severe bending around anatomical structures. After fully entering the housing, the tip 12a is rotated less than 45 degrees to grip housing flanges 11 with tip flanges 42 (Figs. 11B, 12A and 12B). Rotation is accomplished by manually twisting the catheter tubing extension 51, and rotation is limited by stop flanges 45 (Fig. 10). The catheter extension 51 is sufficiently long to provide extracorporeal gripping length and to facilitate hygienic disposal of urine drained through the lumen 41 (Fig. 9A) and catheter lumen 52 (Fig. 9C). Tip 12a is disengaged from the valve by counter rotating until stop flanges 45 again interfere with housing flanges 11 and then extracted by pulling the catheter extension 51.

Referring to Fig. 12A, the valve 1 of the present invention is shown in the distal end bulge 61 of a simplified malecot 62 tipped stent 60 having catheter segment 63 as described in U.S. Patent No. 6,066,088, and simplified by elimination of stent end flanges. Insertion/extraction tool 12 is shown fully engaged with valve 1. Catheter extension 51 is shown truncated for purposes of illustration.

Referring to Fig. 12B, the valve 71 and stent 60 of the U.S. Patent No. 6,066,088, are

shown having a housing 109 having a spherical magnetic valve element 110, fixed nonferromagnetic valve seat 111, ferromagnetic ring 112, and nonmagnetic retaining ring 113, as described in U.S. Patent No. 6,066,088, which is herein incorporated by reference. The improvement being the space of gap 114 provided by the extension of housing 109 between ring 112 and an outlet port identical as at distal end 2a of housing 2, described earlier, with flanges 11, such that the tip 12a of tool 12 can engage the housing 109. The outlet end of the valve is located at the distal end of stent bulge 60a. In this manner, the insertion/extraction tool 12 can be used with the intraurethral magnetic valve of this patent to implant, extract, and manipulate the housing 109 in the urethra. (Such flange 11 may also be incorporated in spring retaining ring 135 in Figs. 5 and 6 of U.S. Patent No. 6,066,088, to similarly provide use with tool 12). Similarly, the flanges 11 may be incorporated in other devices for placement of devices in a patient. Unlike U.S. Patent No. 6,066,088, the housing 2 of the present invention permits simplification of the stent, elimination of retaining ring 135 in Figs. 5 and 6 of U.S. Patent No. 6,066,088 in alternate pressure relief embodiments, and provides more robust gripping and manipulation means built into the valve independent of the stent. As a result, difficult urethral manipulations at higher force levels are possible and stent construction is simplified. Insertion/extraction tool 12 is shown in FIG. 12B fully engaged for manipulation of valve 71 and stent 60. Catheter extension 51 is shown truncated for purposes of illustration. Valve 71 (or valve 1) is secured in stent 60 by elastic tension of the stent rubber, adhesives, or both.

Referring to Fig. 12C, the housing 2 of the present invention is shown in the distal end of a typical stent without a valve. Fig. 12C illustrates that the housing 2 (or flanges 11 thereof) may be incorporated in other biocompatible device with or without a valve to facilitate use with tool 12.

Referring to Figs. 13A and 13B, an optional irrigation pressure regulating washer 80 is shown in axial and sectional views respectively and affixed tip 12a to the insertion/extraction tool 12 in Fig. 13C. The washer is made of biocompatible elastomeric material so that, when needed, it may be stretched over tip 12a flanges 42 and clamp on cylindrical segment 43 and stop flanges 45 as shown in Fig. 13C. Hole 81 fits snugly around tip 12a cylindrical segment 43 and slots 82 fit snugly to flanges 45. Washer 80 is conical so that misaligned engagement of housing 2 and tip 12a remains possible when washer 80 is installed. Washer 80 is thinner than the excess engagement space 66, Fig. 12A, providing a loose fit between tip 12a and housing 2. As such, it will not jam tip and housing together and it will not entirely seal the gap between them. The washer will add significant fluid drag through gap 66, effectively raising the pressure of irrigation water delivered through catheter lumen 51 and tip lumen 41.

Although the above stent 60 is described, the valve assembly 1 may be placed in the distal end of other catheter stents and provide a remotely actuated valving function with high-pressure relief to those stents. Further, the housing 2 may be placed in stents, valved stents, and other appliances, and in conjunction with the tool 12 provide an effective means for placing and manipulating those devices within the urethra or other bodily lumen. Moreover, other valve apparatus than described herein may be placed in the housing 2 which may, in conjunction with the tool 12, provide an effective means for placing and manipulating those valves within the urethra or other bodily lumen.

It will be apparent to those skilled in the art that the valve assembly 1, housing 2, and insertion/extraction tool 12 of the present invention can be used in other environments not exclusive to the human body or human urethra, such as other bodily lumen, not limited to humans or mammalian species, and fluid flow applications where placement of stemless, remotely controllable valves into piping is needed.

In summary, a simple valve housing and insertion/extraction tool have been described for gripping and manipulating stents, valves and valved stents to both implant and extract these from the urethra. Gripped stents or valves can be guided by palpation of the perineum and by tactile feedback of resistance and muscle tone from the external sphincter and other anatomical structures. The insertion/extraction tool provides immediate confirmation of proper stent placement at the bladder neck by permitting urine flow during placement by applying the switch magnet 50, e.g., as along the perineum, to open the valve described herein, or such as when used with U.S. Patent Nos. 5,366,506 and 6,066,088. The tool further permits irrigation and back flushing. The housing and insertion tool are further capable of accommodating gross misalignment caused by bends and anatomical structures within the urethra, assuring trauma free engagement with stent or valve during extraction.

From the foregoing description, it will be apparent that there has been provided an improved intraurethral magnetic valve, housing, and insertion/extraction tool. Variations and modifications to the herein described valve, housing, and insertion/extraction tool in accordance with the invention will undoubtedly suggest themselves to those skilled in the art. Accordingly, the foregoing description should be taken as illustrative and not in a limiting sense.